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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,624	09/05/2006	Jorg Fruchtel	33596-US-PCT	3300
74479	7590	05/11/2009	EXAMINER	
Novartis Animal Health US Inc. 3200 Northline Avenue, Suite 300 Greensboro, NC 27408			KLINKEL, KORTNEY L	
			ART UNIT	PAPER NUMBER
			1611	
			MAIL DATE	DELIVERY MODE
			05/11/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/591,624	FRUCHTEL ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Kortney L. Kinkel	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 24 February 2009.
- 2a) This action is **FINAL**.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-24 and 27-36 is/are pending in the application.
- 4a) Of the above claim(s) 1-21 and 24 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 22,23 and 27-36 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 2/24/2009.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

***Status***

Receipt is acknowledged of remarks and amendments filed 2/24/2009. Claims 22, 24, and 27 were amended. Claims 31-36 were newly added. Claims 1-24, and 27-36 are pending. Claims 1-21 and 24 remain withdrawn pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter. Applicant's elected without traverse, Group II, claims 22-23 and 27-30 in the response dated 7/14/2008. Please note method claim 24 was inadvertently listed as rejected in the Office action dated 10/24/2008.

Claims 22-23, 27-36 are under consideration in the instant Office action to the extent that they read on the elected species, 4,6-bis(4-fluoro-3-(trifluoromethyl)phenoxy)pyrimidin-5-ylamine (the compound of Example 3 of the specification at page 29, also compound 1.9 in Table 1, page 31 and now also, the subject of claim 34).

***Information Disclosure Statement***

Acknowledgement is made of applicant's submitting information disclosure statements on 2/24/2009. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 35 recites “wherein the **endoparasites** are ticks...” There is insufficient antecedent basis for this limitation. Claim 27, upon which claim 35 depends recites an **ectoparasitical** composition, there is no mention of any **endoparasites**.

### ***Claim Rejections - 35 USC § 102***

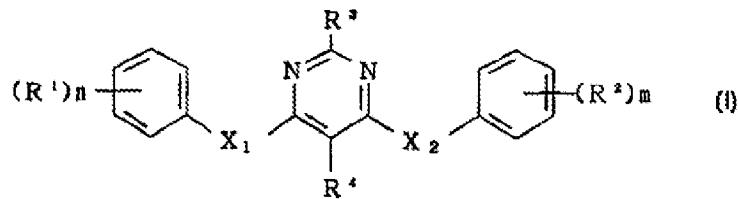
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

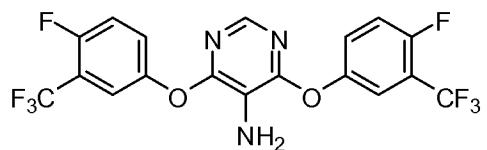
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22-23 and 27-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Hamamoto et al. (WO 98/54154, as per Applicants' IDS).

Hamamoto teaches compounds of formula (I), see below, wherein R<sup>1</sup> and R<sup>2</sup> independently represent halogeno, and C<sub>1-6</sub> haloalkyl, *inter alia*, n and m represent an integer from 1 to 5, R-3- represents hydrogen *inter alia*, R<sup>4</sup> represents NR<sup>5</sup>R<sup>6</sup> *inter alia*, and X<sub>1</sub> and X<sub>2</sub> each independently represent O or NR<sup>11</sup>, and their use as pesticides, which implies the presence of a carrier (abstract).



Specifically Hamamoto teaches Applicants' elected species, 4,6-bis(4-fluoro-3-(trifluoromethyl)phenoxy)-pyrimidin-5-ylamine (Compound 1, Table 1, page 30),



With respect to the newly added limitation in independent claim 22 and 27 "for administration to a non-human animal", this limitation in addition to the preamble recitation of the phrase "an ectoparasiticidal composition", are recitations of the intended use of the claimed composition. The intended use of a claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant situation, because the composition of Hamamoto is comprised of the same ingredients as required by the instant claims, it follows that it would necessarily be capable of being ectoparasiticidal and being administered to a non-human animal. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir.

1990). This same reasoning applies to claims 35 and 36 which recite wherein the enoparasites are ticks and the non-human mammal is a warm-blooded animal, and wherein said formulation is applied locally on a small area of the non-human animal but gives protection or treatment to almost any part of said non-human animal, respectively. Which is to say that the composition would necessarily meet these intended use limitations since the composition taught by Hamamoto is identical in form to that being claimed.

### ***Response to Arguments***

Applicant's arguments filed 2/24/2009 with respect to the rejection of claims have been fully considered, but are not persuasive.

Applicant acknowledges that Hamamoto et al. (WO 98/54154) teaches that the various compounds, including the elected species are pesticides and applicant argues that Hamamoto et al. fails to teach or disclose an ectoparasiticidal composition and therefore this reference cannot anticipate the claims. This argument is not persuasive. The recitation "ectoparasiticidal" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). In this situation, because the composition of Hamamoto is comprised of the same ingredients as required by the instant claims, it follows that it would

necessarily be capable of being ectoparasiticidal and being administered to a non-human animal. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

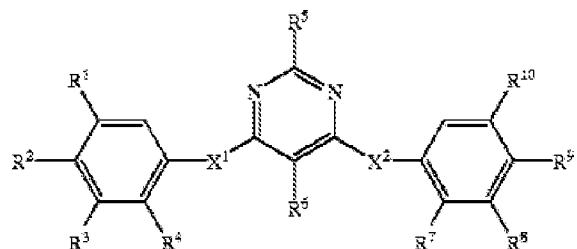
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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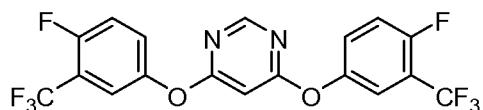
under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22-23 and 27-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Black (US 6342499, as per Applicants' IDS) in further view of Patani et al (Chem. Rev. 1996, 96, 3147-3176).

Black teaches compounds of the following generic structure wherein R<sup>2</sup> and R<sup>9</sup> are F, *inter alia*, X<sup>1</sup> and X<sup>2</sup> are O, *inter alia*, and R<sup>3</sup> and R<sup>8</sup> are C<sub>1-6</sub> haloalkyl, *inter alia*, and all remaining variables are H, *inter alia* (column 2 lines 1-44), and their use as pesticides, namely as anti-mite agents.



One of Black's working examples is drawn to the compound 4,6-bis[( $\alpha,\alpha,\alpha,4$ -tetrafluoro-m-tolyl)oxy]pyrimidine, which has the following structure (Table 1).



This compound differs from that of the instantly elected compound in that an -NH<sub>2</sub> is missing in the 5-position.

Patani et al. teach that amino and hydrogen are bioisosteres (page 5152, section 4).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to arrive at the instant compound with a reasonable expectation for success. Black teaches a compound that is structurally very similar to the instant compound which is also used for the same purpose, namely that as a pesticide. The compounds only differ in the substitution at the 5-position. Patani teaches that hydrogen and -NH<sub>2</sub> are functional equivalents. Accordingly, one of ordinary skill in the art would expect the compound with the -NH<sub>2</sub> and the -H in the 5-position to possess similar properties.

With respect to the newly added limitation in independent claim 22 and 27 "for administration to a non-human animal", this limitation in addition to the preamble recitation of the phrase "an ectoparasiticidal composition", are recitations of the intended use of the claimed composition. The intended use of a claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant situation, Black in view of Patani teach compositions of identical composition as instantly claimed. Because the composition of Black in view of Patani is comprised of the same ingredients as required by the instant claims, it follows that it would necessarily be capable of being ectoparasiticidal and being administered to a non-human animal. "Products of identical chemical composition can not have mutually

exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). This same reasoning applies to claims 35 and 36 which recite wherein the enoparasites are ticks and the non-human mammal is a warm-blooded animal, and wherein said formulation is applied locally on a small area of the non-human animal but gives protection or treatment to almost any part of said non-human animal, respectively. Which is to say that the composition would meet these intended use limitations since the composition taught by Black in view of Patain is identical in form to that being claimed.

Applicants' data in the specification has been considered. Applicants' state that compound 1.9, the elected species, shows an efficacy against the mite, *Ctenocephalides felis* of more than 80% at 100 ppm. Applicants have no other data for this compound against any other parasite. Because Black teaches a compound that is useful as an anti-mite agent and is structurally very similar to the instant compound, differing only in the 5-position and Patani teaches that hydrogen and -NH<sub>2</sub> are bioisosteres, one of ordinary skill in the art would expect the instant compound to show similar functionality to Black's compound. This is, in fact, what is observed. Both Black's compound and the instant compound are anti-mite agents. Accordingly, no unexpected results exist.

***Response to Arguments***

Applicant's arguments filed 2/24/2009 with respect to the rejection of claims have been fully considered, but are not persuasive.

Applicant acknowledges that Black et al. (US 6342499) in view of Patani et al. (Chem. Rev. 1996, 96, 3147-3176) teach that the various compounds, including the elected species have pesticidal action and applicant argues that Black in view of Patani fail to teach or disclose an ectoparasiticidal composition and therefore this reference cannot anticipate the claims. This argument is not persuasive. The recitation "ectoparasiticidal" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). In this situation, because the composition taught by Black and Patani is comprised of the same ingredients as required by the instant claims, it follows that it would be capable of being ectoparasiticidal and being administered to a non-human animal. Furthermore, since Black teaches that the structurally similar compounds have function against mites, which are ectoparasites, one would expect the claimed compound, made obvious in view of the teachings of Patani, to also have function against ectoparasites.

### ***Conclusion***

Claims 22-23 and 27-36 are rejected. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kortney Klinkel, whose telephone number is (571)270-5239. The examiner can normally be reached on Monday-Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KLK

/Sharmila Gollamudi Landau/  
Supervisory Patent Examiner, Art Unit 1611